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10/619,905

07/15/2003

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EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                                   |  |
|------------------------------|-------------------------------|-----------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/619,905 | Applicant(s)<br>BOUMEDIENE ET AL. |  |
|                              | Examiner<br>Timothy P. Thomas | Art Unit<br>1614                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 57-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/25/2007, 9/6/2007, 9/19/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicants' arguments, filed 9/6/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments filed 9/6/2007, with respect to the written description rejection of "furan derivatives" under 35 USC 112 1<sup>st</sup> paragraph have been fully considered but they are not persuasive. The rejection of claims 44-45 is withdrawn, since those claims have been cancelled; however, the rejection is maintained for the reference to "furan derivatives" in claims 60, and dependent claim 61, as follows:

Claims 60-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the use of the term "furan derivatives" in the restriction requirement implies that the term is fundamentally known. The issue is not whether extracts of avocado oil contain furan derivatives, as taught by the Farines, et al. reference (JAOCS; 1995; 72(4): 473-476; IDS 9/6/2007 reference B2). The instant claims indicate that the avocado oil unsaponifiable component contains a fraction that

has been enriched with unspecified furan derivatives in one embodiment. In such a use, the term indicates any of an extremely large possible number of compounds that are furan derivatives, a large genus that applicant does not have written description support for.

3. The previous rejections under 35 USC 112, 2<sup>nd</sup> paragraph; 102 (e); and 103 (a) are withdrawn, due to the claim amendments. The following rejections apply to the new claims and are necessitated by the addition of the new claims.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 57-63, 66, and 68 are rejected under 35 U.S.C. 102(a) as being anticipated by Maheu, et al. ("Symptomatic Efficacy of Avocado/Soybean Unsaponifiables in the Treatment of Osteoarthritis of the Knee and Hip"; 1998 Jan; Arthritis & Rheumatism; 41(1); 81-91).

Maheu teaches a clinical trial of avocado/soybean unsaponifiables (ASU) in the treatment of patients with symptomatic osteoarthritis of the knee or hip (title; Objective); ASU are made of unsaponifiable fractions of 1/3 avocado oil and 2/3 soybean oil (weight ratio avocado/soy is 0.5; p. 82, 2nd paragraph); 63 women with a mean age of

63.3 received ASU treatment (Table 1, p. 85); 300 mg capsules of ASU were administered orally (p. 83, 1<sup>st</sup> paragraph).

It is noted that Maheu does not mention osteoporosis. However, an analysis of the prevalence of individuals with osteoporosis and osteoarthritis indicates that about 3 of the women in Maheu's trial would have had both conditions. Woolf, et al. ("Burden of major musculoskeletal conditions: 2003; Bulletin of the World Health Organization 81:646-656) teaches osteoarthritis affects 18% of women age >60 years (abstract) and 30% of postmenopausal white women in the USA are estimated to have osteoporosis in at least one skeletal site (p. 651, 1<sup>st</sup> paragraph); in the United Kingdom the estimate is that around 23% of women aged 50 years or greater have osteoporosis (p. 651, 1<sup>st</sup> paragraph); percentages increase with age (Figure 3; Table 3; p. 651, 1<sup>st</sup> paragraph). The number of women with both conditions may be calculated as  $(0.18 \times 0.30 \times 63 = 3.4)$  or  $(0.18 \times 0.23 \times 63 = 2.6)$ ; the average of these two calculations, taken as the minimum estimated number of women in the Maheu clinical trial with osteoporosis, is 3. Therefore, the teaching of Maheu inherently includes the treatment individuals with osteoporosis.

The specific components recited in claims 58-61 and 63 would be inherent components in the mixture of the extracts of avocado oil and soybean oil taught by Maheu; especially considering the inclusionary language, "comprises". A fraction enriched with the furan compounds taught by Farines, et al. (JAOCS; 1995; 72(4): 473-476; IDS 9/6/2007 reference B2) would be contained in the avocado unsaponifiable component.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 57, 64-65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maheu, et al. ("Symptomatic Efficacy of Avocado/Soybean Unsaponifiables in the Treatment of Osteoarthritis of the Knee and Hip"; 1998 Jan;

Arthritis & Rheumatism; 41(1); 81-91) and Rancurel (US 5,498,411; cited in previous Office Action).

Claim 57 is rejected as described above. With respect to claims 64-65 and 67, Rancurel teaches a method of preparing nonsaponifiable matter of avocado oil (title; abstract) and similar extracts of soya bean oil is compared (col. 1, lines 45-52); that the nonsaponifiable matter may be used as an active ingredient in pharmaceutical or food industries and provides comfort in the elderly in particular (col. 1, lines 33-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the avocado/soybean unsaponifiable mixture as a food additive, especially to elderly individuals that have difficulty swallowing the capsules taught by Maheu. The proportions taught in claim 65 would also have been obvious to one of ordinary skill in the art at the time of the invention; administration of the 300 mg dose taught by Maheu in 1.5-300 g food corresponds to the percentages of instant claim 65. A single serving of food or a drink of juice would fall within the proportion range of the claim and deliver the doses taught by Maheu. The motivation to administer avocado/soybean oil unsaponifiable as a food additive is suggested by Rancurel, to provide comfort to the elderly who are able to ingest the active mixture with food, but unable to swallow capsules.

### ***Conclusion***

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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/TPT/  
Timothy P. Thomas  
Patent Examiner

  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**